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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/830,761 | 06/18/2001 | Rolando Barbucci | 1756 | 2132 |

7590 05/14/2004
Walter H Schneider
21530 Beechwood Road
Circleville, OH 43113

EXAMINER

WHITE, EVERETT NMN

| | |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1623

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|-----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/830,761 | BARBUCCI ET AL. | |
| | Examiner | Art Unit | |
| | EVERETT WHITE | 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 15, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 15, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed December 18, 2003 and supplemental amendment filed January 21, 2004 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) New Claim 19 has been added;
 - (B) Claims 1-11, 13, 14, 16 and 17 have been canceled;
 - (C) Claims 12 and 18 have been amended;
 - (D) Comments regarding Office Action have been provided drawn to:
 - (a) 102(b) rejection, which has been maintained; &
 - (b) 102(e) rejection, which has been maintained.
2. Claims 12, 15, 18 and 19 are pending in the case.
3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

4. Claims 15, 18 and 19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Pouyani et al (US Patent No. 5,616,568) for the reasons already of record in the previously filed Office Actions.
5. Claims 15, 18 and 19 stand rejected under 35 U.S.C. 102(e) as being anticipated by Prestwich et al (US Patent No. 5,874,417) for the reasons already of record in the previously filed Office Actions.

Claim Rejections - 35 USC § 103

6. Claims 12, 15, 18 and 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Prestwich et al (US Patent No. 5,874,417) in view of Galin et al (US Patent No. 5,944,753) for the reasons already of record in the previously filed Office Actions.

Arguments

7. Applicant's arguments filed December 18, 2003 have been fully considered but they are not persuasive. Applicants amended Claim 18 by inserting language, which set forth "cross-linkage occurs only through amino bonds between carboxy groups of the

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hyaluronic acid and the amino groups of a diamine” and argues that the language overcomes the rejection of the claims. The language inserted into the claims is acceptable, however, the rejections of the claims over the references of record are maintained since the references used to reject the claims set forth cross-linked hyaluronic acid, which is carried out by reacting the carboxy group of hyaluronic acid with the amino groups of a dihydrazide compound. The diamine compound of the instant claims encompasses the dihydrazide compound set forth in the references when the A symbol in the diamine formula “NH₂-A-NH₂” disclosed in Claim 18 is a C₂-C₆ chain which may be substituted with carboxy and other amino groups as set forth in the instant specification and instant Claim 19. For example, see Scheme 1 in column 4 of the Pouyani et al patent and column 7 of the Prestwich et al patent wherein hyaluronic acid is reacted with a dihydrazide, which embraces the instantly claimed diamine when A in the formula in instant Claim 18 is represented as a C₂-C₆ chain and substituted with carboxy and amino groups as set forth in instant Claim 19. The dihydrazido-HA compound in the references is used to produce crosslinked hyaluronic acid compounds. Accordingly, the rejection of the claims under 35 U.S.C. 102 as being anticipated by the Pouyani et al and Prestwich et al patents and the rejection of the claims under 35 U.S.C. 103 as being unpatentable over the Prestwich et al patent in view of the Galin et al patent is maintained for the reasons of record.

8. The rejection of the claims under 35 U.S.C. 103 as being unpatentable over the Prestwich et al patent in view of the Galin et al patent was intended as a new ground of rejection over the claims, which was needed to reject the subject matter of instant Claim 12. It should have been made clearer that the withdrawal of the 103 rejection in the last Office Action was in reference to the previously filed 103 rejection presented prior to the last Office action.

Summary

9. All the pending claims are rejected.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information


11. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


E. White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600